

**§ 58-3-255. Coverage of clinical trials.**

(a) As used in this section:

- (1) "Covered clinical trials" means phase II, phase III, and phase IV patient research studies designed to evaluate new treatments, including prescription drugs, and that: (i) involve the treatment of life-threatening medical conditions, (ii) are medically indicated and preferable for that patient compared to available noninvestigational treatment alternatives, and (iii) have clinical and preclinical data that shows the trial will likely be more effective for that patient than available noninvestigational alternatives. Covered clinical trials must also meet the following requirements:
  - a. Must involve determinations by treating physicians, relevant scientific data, and opinions of experts in relevant medical specialties.
  - b. Must be trials approved by centers or cooperative groups that are funded by the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, the Agency for Health Care Research and Quality, the Department of Defense, or the Department of Veterans Affairs. The health benefit plan may also cover clinical trials sponsored by other entities.
  - c. Must be conducted in a setting and by personnel that maintain a high level of expertise because of their training, experience, and volume of patients.
- (2) "Health benefit plan" is defined by G.S. 58-3-167.
- (3) "Insurer" is defined by G.S. 58-3-167.

(b) Each health benefit plan shall provide coverage for participation in phase II, phase III, and phase IV covered clinical trials by its insureds or enrollees who meet protocol requirements of the trials and provide informed consent.

(c) Only medically necessary costs of health care services, as defined in G.S. 58-50-61, associated with participation in a covered clinical trial, including those related to health care services typically provided absent a clinical trial, the diagnosis and treatment of complications, and medically necessary monitoring, are required to be covered by the health benefit plan and only to the extent that such costs have not been or are not funded by national agencies, commercial manufacturers, distributors, or other research sponsors of participants in clinical trials. Nothing in this section shall be construed to require a health benefit plan to pay or reimburse for non-FDA approved drugs provided or made available to a patient who received the drug during a covered clinical trial after the clinical trial has been discontinued.

(d) Clinical trial costs not required to be covered by a health benefit plan include the costs of services that are not health care services, those provided solely to satisfy data collection and analysis needs, those related to investigational drugs and devices, and those that are not provided for the direct clinical management of the patient. In the event a claim contains charges related to services for which coverage is required under this section, and those charges have not been or cannot be separated from costs related to services for which coverage is not required under this section, the health benefit plan may deny the claim. (2001-446, s. 3.1.)